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EXAMINER WINKLE

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the following document(s)in re Application of David S. Burt, et al., Application No. 09/788,280, filed February 15, 2001 for PROTEOSOME INFLUENZA VACCINE is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Document(s) Attached

1. Amendments to Claims

As we discussed by phone, here are the proposed claims.

No fee is believed due in connection with this transmittal. However, if any fee is due, the Assistant Commissioner is hereby authorized to charge the cost of such fees due in connection with the filing of this document, or to credit any overpayment to Deposit Account No. 20-1430, referencing docket no. 021989.000410US.

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Dated: December 16, 2003 Karen Babyak Dow
Karen B. Dow

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AMENDMENTS TO CLAIMS

Claim 1 (Currently amended) A method to prepare a vaccine effective against ~~viral~~ an influenza infection which method comprises:

providing a mixture of at least one ~~viral protein~~ hemagglutinin (HA) antigen with a proteosome preparation in the presence of detergent, wherein the ratio of proteosomes to antigen is ~~greater than 1:1~~ 2:1 or greater;

removing detergent from said mixture by diafiltration or ultrafiltration to obtain a proteosome-antigen composition, and

formulating said composition into a vaccine.

Claims 2-4 (Cancelled)

Claim 5 (Currently amended) The method of claim 1 wherein said ratio is ~~at least~~ 4:1.

Claim 6 (Currently amended) The method of claim 1 which includes more than one ~~viral~~ HA antigen.

Claims 7-8 (Cancelled)

Claim 9 (Currently amended) A vaccine prepared by the method of any of claims ~~1-8~~ 1, 5 or 6.

Claim 10 (Currently amended) An influenza vaccine which comprises at least one influenza hemagglutinin (HA) formulated with proteosomes in the substantial absence of detergent, wherein the formulation ratio of proteosomes to influenza HA is ~~greater than 1:1~~ 2:1 or greater.

Claim 11 (Original) The vaccine of claim 10 wherein said HA and proteosomes are in the form of particles with a median size in the range of 150-1,000 nM as measured by light scattering.

Claims 12-13 (Cancelled)

Claim 14 (Currently amended) A method to prepare a multivalent vaccine effective against ~~viral~~ an influenza infection which method comprises:

providing a mixture of at least two ~~viral protein~~ hemagglutinin HA antigens to a proteosome preparation in the presence of detergent wherein the ratio of proteosomes to antigens is ~~greater than 1:1~~ 2:1 or greater; and

removing detergent from said mixture by diafiltration or ultrafiltration to obtain a proteosome-multivalent antigen composition, and

formulating said composition into a vaccine.

Claims 15-17 (Cancelled)

Claim 18 (Currently amended) The method of claim 14 wherein said ratio is ~~at least~~ 4:1.

Claims 19-29 (Cancelled)

Claim 30 (Original) The method of claim 1 wherein said detergent comprises more than one detergent.

Claim 31 (Previously presented) A composition prepared as described in claim 1 which is filtered with a 0.2 or 0.8 μm filter.

Claim 32 (Cancelled)

Claim 33 (Previously presented) A composition prepared as described in claim 14 which is filtered with a 0.2 or 0.8 μm filter.

Claims 34-57 (Cancelled)

Claim 58 (Currently amended) An influenza vaccine which comprises at least one influenza hemagglutinin (HA) formulated with proteosomes in the substantial absence of detergent, wherein the formulation ratio of proteosomes to influenza HA is ~~at least~~ 4:1.

Claim 59 (New) The method of claim 1 wherein said ratio is 2:1.

Claim 60 (New) The method of claim 14 wherein said ratio is 2:1.

Claim 61 (New) An influenza vaccine which comprises at least one influenza hemagglutinin (HA) formulated with proteosomes in the substantial absence of detergent, wherein the formulation ratio of proteosomes to influenza HA is 2:1.

Claim 62 (New) An influenza vaccine which comprises at least three influenza hemagglutinin (HA) antigens formulated with proteosomes in the substantial absence of detergent, wherein the formulation ratio of proteosomes to influenza HA antigens is 2:1.

Claim 63 (New) An influenza vaccine which comprises at least three influenza hemagglutinin (HA) antigens formulated with proteosomes in the substantial absence of detergent, wherein the formulation ratio of proteosomes to influenza HA antigens is 4:1.